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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,693	01/14/2002	Hans Rudolf Muller	EPROV 18	8617

23599 7590 12/29/2003

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.  
2200 CLARENDON BLVD.  
SUITE 1400  
ARLINGTON, VA 22201

EXAMINER
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TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 12/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n No.

10/030,693

Applicant(s)

MULLER ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,2,6,7,10-12,14 and 16-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,10-12,14,16,17,19,20 and 23 is/are allowed.
- 6) ☒ Claim(s) 2,6, 7, 18,21 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### FINAL ACTION

Applicant's amendment of 10-17-03 has been fully considered. The amended claims have overcome the previous rejections of 112/2<sup>nd</sup> paragraph and 102. However, the amended claim 2 introduces new matter. Furthermore, the teaching of Müller et. al. still reads on new claims 18, 21, and 22. Thus, the amendment necessitates the following new ground(s) of rejections.

Claims 3-5, 8, 9, 13, and 15 have been cancelled, leaving claims 1, 2, 6, 7, 10-12, 14, 16-23.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 2, 6, and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2 and 6 recite the phrase "satisfy formula...". The word "satisfy" renders the claims indefinite because it is unclear what the metes and bounds are. That is, it is unclear if all limitations of formula III must be met, or only some limitations need to be met. Claim 7 is rejected as being dependent on claim 6.

Applicant is suggested to replace said phrase with the phrase "of formula..."

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 18, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by **Müller et. al.** (US'836). In Examples 1, 4, and 5, **Müller et. al.** describe a process of separating diastereomers of tetrahydrofolic acid that reads on the above claims with the following limitations:

- a. Diastereomers of tetrahydrofolic acid (or formula III with R<sub>1</sub> and R<sub>2</sub> as hydrogen atoms) react with aromatic sulphonic acid (i.e., toluene-p-sulfonic acid); see Example 1, line 55,
- b. The process is carried out in an organic solvent of mercaptoethanol at 60°C (see Example 1, line 50) or N,N'-dimethylformamide at 27°C (see Example 5, line 65).
- c. In Example 1 where the mixture is heated to 60°C, the solution is cooled down before crystallization. This additional step reads on the instant claim 21 where heating is involved.
- d. The additional step of crystallizing, followed by hydrolyzing with a base, and crystallizing the free acid is also described in Example 1 (lines 64-68). These additional steps reads on the instant claim 22.

Note, even though claims 18 and 22 do not specifically recite 'heating', they recite 'dissolving' which suggests 'heating' may be involved.

Thus, the disclosed process reads on all limitations of the claims.

### ***Specification***

3. The disclosure is objected to because of the following informalities: The specification uses the phrase "satisfy formula..." or "satisfies formula..." in several places, which seems unclear as to the scope of "satisfy" or "satisfies". It is suggested that said phrases be replaced with the phrase "of formula..."

Appropriate correction is required.

### ***Allowable Subject Matter***

4. Claims 1, 10-12, 14, 16, 17, 19, 20, and 23 are allowed. The teaching of Müller et. al. (US'836) does not suggest a process of separating the diastereomers of tetrahydrofolic acid esters. That is, the preparation of Müller et. al. does not start with tetrahydrofolic acid esters.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

Art Unit: 1624

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (7 am -12 pm, and 3 pm - 6 pm) starting from 10-1<sup>st</sup> -03.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



T. Truong

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December 23, 2003

  
JEAN F. VOLLANO  
PRIMARY EXAMINER  
Art Unit 1624